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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,399	12/05/2003	Jerry R. Colca	01455/1	8615

7590 04/28/2006

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EXAMINER	
BOWMAN, AMY HUDSON	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 04/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/728,399	COLCA, JERRY R.	
	Examiner	Art Unit	
	Amy H. Bowman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *16-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/3/05, 2/9/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse of group I, claims 1-15, and SEQ ID NO: 1, in the reply filed on 2/9/2006 is acknowledged.

Applicant asserts that the examiner has failed to show there is an undue burden. Applicant seems to rely on the fact that the withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04 to establish that there is not an undue search burden.

Contrary to applicant's assertion, until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained, as explained in the office action mailed 5/12/2005. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996) for further explanation of product and process claims. Simply because the process claims may be rejoined upon determination that the product claims are allowable does not mean that there is not a search burden to examine the two groups together before the product claims are found allowable.

The requirement for restriction is still deemed proper and is therefore made FINAL.

Claims 16-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Additionally, the subject matter of claims 3-6 that is not drawn to the

elected invention, SEQ ID NO: 1, has been withdrawn as being drawn to nonelected inventions. Applicant timely traversed the restriction (election) requirement in the reply filed on 2/9/2006.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites, "consists of at least 8 contiguous..." The terminology "consists of" constitutes closed language, so the language "consists of" coupled with "at least" is contradictory language within the claim . Appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The invention of the above claims is drawn to an antisense compound targeted to a nucleic acid molecule encoding mitoNEET, wherein said antisense compound specifically hybridizes with and inhibits the expression of mitoNEET.

At the outset, it is noted that the claims do not recite a specific target nucleotide sequence by SEQ ID NO, but rather refers to the broad genus of mitoNEET sequences.

The claims encompass any antisense oligonucleotide 8 to 30 nucleobases in length targeted to any nucleic acid molecule encoding any mitoNEET. The claims encompass antisense oligonucleotides targeting any mitoNEET RNA, as well as any mitoNEET homolog or allele known or yet to be discovered from any species of mitoNEET, as well as DNA genomic fragments, splice variants or polynucleotide fragments that express proteins that retain mitoNEET -like activity.

The specification refers to "mitoNEET" as a family of polypeptides (see page 1 of the instant specification), rather than a specific target sequence. The instant specification does not teach antisense oligonucleotides targeted to a family of polypeptides, but rather to the human mitoNEET sequence disclosed as SEQ ID NO: 624. Although the specification discloses specific oligonucleotide sequences targeted to instant SEQ ID NO: 624, the specification does not describe oligonucleotides directed to any other species or variant of mitoNEET to describe the instantly claimed genus of the broad claims which encompass any mitoNEET target sequence. It is the structure of each specific oligonucleotide that leads to its function with regards to a specific target sequence. One of ordinary skill in the art could not make such oligos targeted to any mitoNEET without knowledge of the sequence. Given the breadth of sequences

embraced in the instantly claimed genus, one could not envision the member oligonucleotides that target such a broad genus.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-15 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial utility or a well established utility.

The invention of the above claims is drawn to an antisense compound targeted to a nucleic acid molecule encoding mitoNEET, wherein said antisense compound specifically hybridizes with and inhibits the expression of mitoNEET. The compound is further specified to be an antisense oligonucleotide, more specifically SEQ ID NO: 1. The claims are further drawn to a composition comprising the antisense oligonucleotide and a pharmaceutically acceptable carrier or diluent.

The specification discloses asserted utilities for mitoNEET and antisense oligonucleotides targeted to mitoNEET. The specification discloses that mitoNEET is likely to have therapeutic uses in a variety of cardiovascular, endothelial, and angiogenic disorders, including systemic disorders that affect vessels, such as diabetes mellitus (see paragraph 30 of the instant specification). The instant specification discloses a multitude of diseases or disorders that mitoNEET could have a therapeutic utility with. The specification further discloses that mitoNEET or modulators thereof are

likely to play an important role in the etiology and pathogenesis of many or all of the disorders noted in the specification (see paragraph 63 of the instant specification).

However, hypothesizing various potential utilities for inhibiting mitoNEET with an antisense oligonucleotide is not sufficient for establishing an actual utility specific for mitoNEET inhibition.

Although the instant specification teaches antisense inhibition of mitoNEET expression, the instant specification only offers support for prophetic examples of what utility there is in inhibiting mitoNEET with an antisense oligonucleotide of the invention.

The specification does not disclose a nexus between any specific disease states and a decrease in the expression of mitoNEET. This deficiency is not compensated for in the art. As evidenced by applicant's own post-filing publication, Colca et al. (Am J Physiol Endocrinol Metab, 2004, 286, pages E252-E260), significant further research would have to be conducted to identify such a nexus. Colca et al. teach that mitoNEET is a novel mitochondrial protein that binds to insulin sensitizing, antidiabetic thiazolodinediones and that mitoNEET is a target for thiazolodinediones. Colca et al. teach that the mechanism of thiazolodinediones is not clearly understood. Colca et al. teach that thiazolodinediones may produce their effect by direct interaction with PPARγ, but that not all PPARγ activators have antidiabetic actions. Colca et al. teach that thiazolodinediones may have different effects in different tissues and that resolution of the key site of thiazolodinedione interaction would undoubtedly help in the production of improved therapeutic agents. Colca et al. also teach that mitoNEET may play a role in regulating mitochondrial oxidation of fatty acids, and modulation of this target may be

involved in the mechanism of action of these drugs. Colca et al. conclude that this hypothesis needs to be tested. The teachings of Colca et al. support that there is not an established utility for mitoNEET, but rather the utility of inhibiting mitoNEET is still being explored. Applicant has offered a multitude of asserted utilities for mitoNEET, but has not taught any specific utility that is not simply prophetic.

Therefore, it is unclear what specific and substantial utility there is in inhibiting mitoNEET with an antisense oligonucleotide of the instant invention.

Claims 1-15 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102 or 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 3, and 5 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Chew et al. (WO 01/79220 A2).

The invention of the above claims is drawn to an antisense compound targeted to a nucleic acid molecule encoding mitoNEET, wherein said antisense compound specifically hybridizes with and inhibits the expression of mitoNEET. The compound is further specified to be an antisense oligonucleotide comprising at least 8 contiguous nucleic acids of a nucleic acid sequence of SEQ ID NO: 1.

Chew et al. disclose a 10 nucleobase oligonucleotide that comprises 8 contiguous nucleic acids of a nucleic acid sequence of instant SEQ ID NO: 1 (see nucleobases 1-8 of SEQ ID NO: 39 of Chew et al.).

The oligonucleotide taught by Chew et al. is an oligonucleotide primer. However, the instant specification does not define an "antisense oligonucleotide" to exclude primers. The instant specification, page 10, defines the term "oligonucleotide" to refer to an oligomer or polymer of ribonucleic acid (RNA) or deoxyribonucleic acid (DNA) or mimetics thereof. Furthermore, the oligonucleotide primer taught by Chew et al. is complementary, or antisense, to the target nucleic acid. Therefore, the oligonucleotide primer taught by Chew et al. meets the instant limitation of an antisense oligonucleotide.

The sequence disclosed by Chew et al. meets all of the structural requirements of the instant claims, so the oligonucleotide would also be expected to target a nucleic acid molecule encoding mitoNEET, as well as specifically hybridize and inhibit the expression of mitoNEET, as instantly claimed, absent evidence to the contrary.

See, for example, MPEP § 2112, which states "[w]here applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. 'There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102.' In re Best, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims."

Therefore, the instant invention is anticipated or obvious over Chew et al.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy H. Bowman whose telephone number is 571-272-0755.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance.

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Amy H. Bowman
Examiner
Art Unit 1635

JAMES SCHULTZ, PH.D.
PRIMARY EXAMINER